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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,188	06/02/2005	Niall Gormley	2713-1-015PCT/US	1232
23565	7590	11/29/2006	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			SHAW, AMANDA MARIE	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 11/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/537,188

Applicant(s)

GORMLEY ET AL.

Examiner

Amanda M. Shaw

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,6-16 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1-26 are currently pending. Applicant's election without traverse of Group II (Claims 4-5 and 17-18) in the reply filed on October 2, 2006 is acknowledged.

Claims 1-3, 6-16, and 19-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Accordingly, Claims 4-5 and 17-18 have been examined herein.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nazarenko et al (US Patent 6090552 Issued 2000).

Nazarenko et al teach a hairpin primer which comprises a double stranded stem region, a single stranded loop region, and an additional single stranded region extending from the 3' end of the hairpin which acts as a primer (See Fig 1). In the presence of a target nucleic acid, the target binds to the single stranded region extending from the 3' end of the hairpin. Thus Nazarenko et al teach a single stranded

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template nucleic acid attached to the 5' end of a hairpin and its complement attached to the 3' end. In the presence of a polymerase and dNTPs the singled stranded region extending from the 3' end of the hairpin is elongated using the target as a template. Nazarenko et al further teach that hairpin nucleic acid has a recognition sequence and a cleavage site and in the presence of a nicking restriction enzyme the elongated strand can be nicked and strand displacement can occur (See Figure 10 and Columns 29-30). Thus the target nucleic acid which is being interpreted as the template nucleic acid is recovered. Additionally the hairpin is being interpreted as a double stranded nucleic anchor because the hairpin probes comprise a double stranded stem region.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nazarenko et al (US Patent 6090552 Issued 2000) in view of Chernov et al (US 2004/0086866 Filed 10/2002).

The teachings of Nazarenko et al are presented above in paragraph 2.

Nazarenko et al do not teach that the hairpin probes are attached to a solid substrate.

However Chernov et al teach the use of hairpin probes attached to a microarray (Para 0013).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Nazarenko et al by using probes which are attached to a solid substrate as suggested by Chernov et al because it was reported that hairpin probes attached to a chip display higher rates of hybridization and larger equilibrium amounts of captured targets in comparison with linear probes. Further hairpin-DNA-target complexes were thermodynamically more stable (Para 0013).

#### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-5 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 10-11, 19-26 of copending Application No. 10537186. Although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, claims 4-5 of the instant application and claims 1-2, 19-20, and 23-24 of copending Application No. 10537186 both encompass methods comprising: providing a single-stranded template nucleic acid attached to the 5' end of a hairpin nucleic acid, wherein the hairpin nucleic acid is self-complementary and has a first restriction site for a nicking endonuclease, said restriction site comprising a recognition sequence and a cleavage site, wherein said recognition sequence is situated so that said cleavage site is before, at, or beyond the 3' end of the hairpin nucleic acid, and wherein said hairpin nucleic acid is a self-hybrid, and wherein a nucleic acid strand complementary to the template nucleic acid is attached to the 3' end of the hairpin nucleic acid. Both sets of claims further encompass subjecting the nicked hairpin-template-complement nucleic acid complex to conditions whereby the nucleic acid strand complementary to the template nucleic acid dissociates from the template nucleic acid; thereby recovering the single-stranded template nucleic

acid. The claims of copending Application No. 10537186 are different from the instant claims because the claims further comprise additional steps which enable one to detect a methylated cytosine in the template nucleic acid. In view of the "comprising" language in the claims of the instant invention the claims of copending Application No. 10537186 anticipate the instant claims even though they include additional steps. Additionally claims 17-18 of the instant application and claims 10-11, 21-22, and 25-26 of copending Application No. 10537186 both encompass methods comprising providing a single-stranded template nucleic acid attached to a double-stranded nucleic acid anchor, and wherein a nucleic acid strand complementary to the template nucleic acid is attached to the double-stranded nucleic acid anchor, and wherein the double-stranded nucleic acid anchor: (i) has a first end and a second end; and (ii) has a first restriction site for a nicking endonuclease, said restriction site comprising a recognition sequence and a cleavage site, wherein said cleavage site is situated so that said cleavage site is before, at, or beyond the 3' end of the first end of the double-stranded nucleic acid anchor; wherein the single-stranded template nucleic acid is attached to the 5' end of the first end of the double-stranded nucleic acid anchor, and wherein the nucleic acid strand complementary to the template nucleic acid is attached to the 3' end of the first end of the double-stranded nucleic acid anchor; Both sets of claims further encompass subjecting the nicked hairpin-template-complement nucleic acid complex to conditions whereby the nucleic acid strand complementary to the template nucleic acid dissociates from the template nucleic acid; thereby recovering the single-stranded template nucleic acid. The claims of copending Application No. 10537186 are different from the instant

claims because the claims further comprise additional steps which enable one to detect a methylated cytosine in the template nucleic acid. In view of the "comprising" language in the claims of the instant invention the claims of copending Application No. 10537186 anticipate the instant claims even though they include additional steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

5. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**